

## **DETAILED ACTION**

### **Election/Restrictions**

Restriction is required under 35 U.S.C. 121 and 372.

#### ***Lack of Unity Requirement***

Restriction is based on PCT Rule 13.1, 13.2 and Annex B part 1(b) together with 37 CFR 1.475 and 1.499 for lacking unity of invention because of lacking a significant structural element qualifying as the special technical features.

Claims 1-23 and 25-28 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2. PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that “special technical features” mean those technical features, which as a whole define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

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- (i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specifically designed for carrying out the said process,. . .”

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-13 and 21-23 drawn to a compound of formula (I) and process of preparing classified in class 548 and several subclasses.
- II. Claims 14-20 and 27 drawn to another process of preparing a compound of formula (I) classified in class 548 and several subclasses.
- III. Claims 25, 26 and 28 drawn to a method of treating a disease classified in class 514 and several subclasses.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features that define a contribution over the prior art. The invention Groups I-III outlined above each relate to a set of structurally diverse and dissimilar compounds, process of preparing and method of uses which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious. Accordingly, the unity

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of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Mr. Jay Cinamon on November 06, 2008 to request an oral election to the above restriction requirement, and a provisional election was made **without traverse** to prosecute the invention of Group I.

Applicants preserve their right to file a divisional on the non-elected subject matter.

#### ***Priority***

This application is a 371 of PCT/EP04/50339 03/22/2004 which claims benefit for foreign priority under 35 U.S.C. § 119(a)-(d) to ITALY MI2003/A000573 03/24/2003, is acknowledged.

#### ***Status of Claims***

Claims 1-23 and 25-28 are currently pending in the application. Claim 24 was canceled.

Claim 14-20 and 25-28 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

***Information Disclosure Statement***

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 02/08/2006, which has been entered in the file.

***Response to Election/Restriction***

In response to the restriction requirement, Applicants have elected Group I, [which includes claims 1-13 and 21-23 drawn to a compound of formula (I) and process of preparing] **without** traverse is acknowledged. However, during a telephonic interview, with Mr. Jay Cinamon (Attorney for Applicant) Applicant has agreed to cancel non-elected claims 14-20 and 25-28 of Groups II and III. Therefore, the restriction requirement is hereby withdrawn and hence, all remaining pending claims 1-13 and 21-23 have been examined and found allowable over the prior art of record.

***Examiner's amendment***

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephonic interview with Mr. Jay Cinamon on November 06, 2008.

The application has been amended as follows:

- a. Claims 14-20 and 25-28 have been canceled.

- b. In claim 1 (Original), page 3, line 4, please delete “or solvates”.
- c. In claim 21 (Original), page 8, lines 2-3, please delete “or solvates”.

***Reasons for allowance***

The following is an Examiner's statement of reasons for allowance:

Claims 1-13 and 21-23 are being allowed since the instantly claimed inventions are neither obvious nor anticipated by the prior art (US 5,053,422, cited) and there is no suggestion or motivation to modify the compound of any prior art to obtain the instantly claimed invention. Therefore, the instant claims 1-13 and 21-23 are found allowable over the prior art of record.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 7:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone number for this Group is (571) 273-8300. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) “Official” for papers that are to be entered into the file, and “Unofficial” for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be

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addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

/Golam M. M. Shameem/

Primary Examiner

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Technology Center 1600

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